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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,437	12/20/1999	ISA ODIDI	10914-11	7273

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/403,437	Applicant(s) ODIDI ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Request for an RCE, received November 29, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 3,870,790 to Lowey *et al.,* in view of US 5,162,117 to Stupak *et al.*, and further in view of US Patent 4,853,249 to Takashima *et al.*.

Lowey *et al.* teach a solid pharmaceutical composition in which the core comprises a pharmaceutical active, and a carrier made of hydroxypropylmethyl cellulose admixed with ethylcellulose (abstract). Lowey *et al.* teach that the formulation will release the active over a prolonged period of time. Lowey *et al.* also allow for the inclusion of various excipients. Lastly, Lowey *et al.* teach that their invention can be used with any active ingredient. They state, "the nature of the therapeutic agent is not critical and any drug, or stable combination of drugs, can be incorporated into these novel pharmaceutical forms." (see c 5, l 59-62). Lowey *et al.* does not teach the specific additives and excipient as claimed by applicant.

Stupak *et al.* is relied upon for the teaching that applicant's claimed excipients are all very well known in the pharmaceutical art, and therefore would have been obvious to include in any pharmaceutical formulation, especially one which has the same function of controlled release. Stupak *et al.* disclose a controlled release solid dosage tablet. More specifically, Stupak *et al.* teach that the tablet core of their invention can include excipients including diluents such as microcrystalline cellulose, lubricants, glidants such as silicon dioxide, as well as sodium lauryl sulfate and lactose (c 2-3). Additionally, Stupak *et al.* teach that their composition can have a coating, which can be a methacrylic acid copolymer coating (c 5, claim 5). Again, the Stupak reference is relied upon to show that applicant's claimed excipients are all known in the art of pharmaceutical formulations, and therefore would be obvious to include in a tablet formulation.

It is the position of the examiner that the main component of applicant's invention is the mixture of polymers in the core of the composition, which is disclosed generally by Lowey *et al.*. Lowey *et al.* does not teach that the hydrophilic polymer be a mixture of hydroxypropylmethylcellulose and hydroxyethylcellulose. However, it is the position of the examiner that because theses two polymers act so similarly, and are often interchangeable in a pharmaceutical composition, it would have been obvious to one of ordinary skill in the art to use one or the other or a mixture of the two hydrophilic polymers. As stated in In Re Kerkhoven, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be

used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Additionally, the Takashima reference is relied on to further exemplify that cellulose derivatives are known in the art to be interchangeable, and useful in combination with each other. More specifically, Takashima *et al.* teach that cellulose derivatives such as ethyl cellulose, hydroxyethyl cellulose, and hydroxypropylmethyl cellulose are useful individually or in combination as a binder in a sustained release composition (c 3, l 4-14).

Therefore, because Lowey *et al.* teach the mixing of HPMC with ethylcellulose, and Takashima *et al.* teach that cellulose derivatives such as HPMC and HEC are useful in combination, it is the position of the examiner that the above combination of references suggests applicant's claimed invention. Further, one of ordinary skill in the art would have been motivated to combine the teachings of Lowey *et al.* and Stupak *et al.*, and use any of the well known pharmaceutical excipients described by Stupak *et al.* in the composition disclosed by Lowey *et al.*. The expected result would be a successful controlled release pharmaceutical composition. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed November 29, 2001 have been fully considered but are not found persuasive. Applicant argues that neither Lowey nor Stupak teaches the

combination of polymers claimed in instant claim 1. Previously the examiner relied upon the knowledge of one of ordinary skill in the art that cellulose derivatives are known to be interchangeable and useful in combination. The examiner has since added the Takashima reference to reiterate this fact.

Furthermore, applicant argues that the combination of references does not teach the unobvious advantages of extended controlled release. Applicant has amended the claim to include a limitation which states that the release lasts for up to at least 20 hours. Applicant further points out that the Lowey reference only teaches release for up to 8 hours. However, the teachings of Lowey still suggest the limitations of applicant's claim, because 8 hours reads on a limitation of up to 20 hours. This limitation includes anything between 0 and 20 hours. Additionally, column 2, lines 31-36 of Lowey clearly states that the release time, the dosage unit and the pattern of release can be controlled by the relative amounts of the HPMC and EC employed.

Lastly, applicant argues that the cited combination of references does not suggest the claimed moisture content of the instant claims. More specifically, instant claim 30 includes a moisture content of the composition which is less than 3%. Applicant argues that Lowey teach a moisture content as high as 25%. However, the examiner would like to point out that Lowey also teaches a moisture content as low as 5% (abstract). The examiner finds no critical difference between 3% and 5%, absent a showing of criticality. Applicant argues that the difference between 3 and 5% is critical, and further states that this difference helps to further extend the release profile of the composition. However, applicant has not submitted any data or experimentation to

support this statement. Absent a showing of criticality, it remains the position of the examiner that there is not a significant or patentable difference between 3 and 5% moisture content.

Lastly, in response to applicant's arguments against the Stupak reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Therefore, the above rejection is maintained and applied to new claim 30.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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